

Compliance Today – December 2021 Ready, set, go—for 2022 Stark group practice compliance!

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It is time for group practices to finalize revisions, if any, to compensation for 2022. Almost one year after the Centers for Medicare & Medicaid Services (CMS) published its final rule amending the Physician Self-Referral Law (Stark Law) regulations,^[1] group practices will soon be expected to comply with the revised version of the special rules for profit shares and productivity bonuses. Despite the extra time CMS afforded group practices to consider and revise their compensation models, complexities of the ongoing pandemic in conjunction with difficulties of everyday life may have left some group practices unprepared for these changes. This article highlights the new group practice regulation, effective January 1, 2022, and is a tool for group practices to use when reviewing and revising their compensation models.

The Stark Law and group practices

The Stark Law is a Medicare billing rule that governs the making of referrals for certain healthcare services and billing for those referrals. Specifically, it prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the DHS. It also prohibits that entity from billing Medicare for those prohibited referrals. If an arrangement implicates the Stark Law, it must fit within an applicable exception. That requirement applies even to arrangements between physicians and their group practices.

The Stark Law recognizes that group practices operate in a fundamentally different way than other entities, such as hospitals. Accordingly, group practices have extra flexibility when it comes to allowable compensation arrangements. Group practices may take advantage of the in-office ancillary services exception, which broadly protects DHS referrals that fit within its requirements.^[2] However, in order to prevent physicians from merely forming loose affiliations to take advantage of the group practice rules and the in-office ancillary services exception, the Stark Law sets forth detailed requirements that must be met in order for an entity to qualify as a group practice.^[3] Those requirements include allowable methodologies for distributing DHS profits to physicians as well as allowable productivity bonuses payable to physicians.^[4]

The final rule

The Stark Law has grown increasingly complex, often resulting in technical traps for providers that lead to major financial liabilities. In response to industry pressure and in an attempt to modernize the Stark Law regulations,

CMS recently undertook amendments to the Stark Law regulations. CMS updated the regulations to allow for value-based and coordinated care payment models and clarify existing terminology and rules that have presented significant burdens to the industry. On December 2, 2020, CMS published its final rule reflecting these changes.^[5]

The majority of the final rule was effective on January 19, 2021. However, group practices voiced concern in response to the proposed rule that the typical 60 day waiting period between publication of a rule to effective date would not provide sufficient time for group practices to evaluate the rule and make necessary revisions. Many group practices reevaluate their compensation methodologies annually. CMS agreed with stakeholders and afforded group practices this delay in response to their concerns.^[6] In doing so, it chose to delay all revisions to the group practice rules so as to avoid complications with restructuring the regulation. Accordingly, the group practice provisions of the final rule were delayed and will now take effective January 1, 2022.

Revised volume or value standard for group practices

The new “volume or value” standard, which was effective with most of the final rule on January 19, 2021, will be applicable to group practices in 2022. That standard describes the universe of compensation that CMS considers to be determined in a manner that takes into account the volume or value of a physician’s referrals. It introduces a formulaic approach to the volume or value determination, in which the relevant test is, in part, whether the group practice uses the physician’s referrals as a variable in their compensation. That would result in compensation that positively correlates with the number or value of the physician’s referrals to the entity.^[7] Group practices may find this standard in the special rules on compensation.^[8]

CMS also clarified that, despite using the terms “based on” and “related to” prior to the volume or value standard, it interprets those to mean “takes into account.”^[9] CMS did not change the regulatory text to conform to the term “takes into account” because the current text mirrors the statutory language. Nonetheless, group practices now have confirmation that those terms are applied as a test to determine whether the volume or value of the physician’s referrals are taken into account in their compensation.

Revisions to accommodate value-based enterprise compensation

CMS added new language to the group practice regulation to accommodate value-based enterprise compensation. As readers may recall, CMS introduced three new exceptions regarding compensation from value-based enterprises in the final rule to further its goal of modernizing the Stark Law regulations as new payment forms and care delivery models gain traction. Group practices may take advantage of those new exceptions as entities that provide DHS. Additionally, group practices will be able to accommodate new payments within the group practice regulation for value-based enterprise activities.

A new subsection will address downstream compensation that derives from payments made to group practices, rather than payments made directly to a physician in the group, that relate to the physician’s participation in a value-based arrangement.^[10] Group practices will not need to use a component of at least five physicians in order to receive and distribute the compensation—a departure from its requirement as it relates to profit shares for distribution of all DHS. A group practice may distribute the profits from DHS furnished by the group that are derived from a physician’s participation in a value-based enterprise directly to that physician in the group, including profits from DHS referred by the physician. Such remuneration will be deemed not to be based on (or take into account) the volume or value of the physician’s referrals. This change is intended to encourage individual physicians in a group practice to participate in a value-based enterprise with healthcare providers outside its own group practice. Compliance officials should take note that this change only addresses

compensation relating to a physician's participation in a value-based arrangement and does not relax the rules relating to distribution of nonvalue-based arrangement profits.

Notably, the distribution must be of profits, not revenue. CMS acknowledged that group practices may have an easier time calculating revenue as opposed to profits. Nonetheless, CMS chose to only permit the distribution of profits directly attributable to a physician's participation in a value-based enterprise. This choice is consistent with CMS's policy view that distributing revenue, as opposed to profits, which are calculated by deducting the expenses incurred in furnishing the DHS, could serve as an inducement for potentially inappropriate referrals.

Clarification regarding the distribution of profit shares

The special rule for profit shares in the group practice regulation allows overall profits from DHS to be distributed to any component of the group practice of at least five physicians.^[11] In the final rule, CMS clarified that this statement allows distribution of profit shares within a group practice of fewer than five physicians.^[12] If a group practice is made up of fewer than five physicians, then the distribution of overall profits derived from all DHS of the group practice should be among all physicians in the group practice. If a group practice is made up of more than five physicians, it may choose to create pods of five or more physicians for purposes of distribution of profits from all their DHS. There is no requirement that a group practice adopt a uniform distribution methodology for all pods in the event the group practice has more than one pod. Accordingly, if a group practice creates multiple pods of least five physicians, it may apply different distribution methodologies across the various pods. Note that within a particular pod, the distribution methodology must be consistently applied to physicians within that particular pod.

CMS clarified that the term "overall profits" means the profits from *all* DHS performed by the group. Accordingly, DHS may not be distributed on a service-by-service basis. Instead, profits from all DHS of the group practice, or a component of at least five physicians in the group practice, must be aggregated prior to distribution. It is worth highlighting that the group practice definition does not require the distribution profits from DHS. It provides the rules, if a group practice chooses to distribute DHS profits, for doing so in compliant manner. Accordingly, if a group practice chooses to distribute DHS profits, it must aggregate all DHS profits prior to distribution.

Group practices that previously distributed profits from DHS revenue on a service-by-service basis must change that methodology effective January 1, 2022. Some group practices may be in a difficult position if those profits are distributed in arrears. In other words, in profits for 2021, DHS are not distributed until 2022. CMS does not specifically address this scenario in the final rule. Group practices may reasonably conclude that because CMS has adopted the approach that arrangements must satisfy an exception at the time the physician makes the DHS referral, compensation payable thereafter would be allowable if the group met the group practice definition in 2021, when the DHS referrals occurred.^[13] This approach is bolstered by CMS's statement that it intends for the final rule to only apply prospectively.^[14] Nonetheless, group practices that adopt this approach may be assuming risk and should consider its unique circumstances prior to paying any compensation.

Finally, CMS introduced various general clarifications to the group practice regulation as it relates to the distribution of profit shares. First, it eliminated the reference to Medicaid in the definition of overall profits. This conforms more closely to the statutory text.^[15] Second, it restructured and renumbered the group practice regulation to better organize the regulation. In doing so, it shifted prefatory language regarding the special rules for distribution of overall profits. It also added consistent references to profit, as opposed to using profit and revenue interchangeably. Streamlining this language is intended to reduce inadvertent confusion of CMS's intent. Finally, CMS clarified language in one of the deemed permissible methods of distributing shares of overall

profits by replacing any reference to DHS payable by any federal healthcare program or private payer with reference to DHS payable by Medicare. This revision reinforces the statutory construct that the Stark Law is a Medicare payment rule and should not be applied to other federal programs. (Theories applying the Stark Law to Medicaid have gained traction through case law in certain jurisdictions, despite the statutory application to only Medicare.)

Clarification regarding productivity bonuses

CMS did not introduce significant changes to the special rule for productivity bonuses; however, it did provide clarification around personal productivity through revisions to the deeming provisions. Deeming provisions articulate the compensation methodologies that CMS considers to not take into account the volume or value of DHS referrals. Deeming provisions are not mandatory and do not list the universe of allowable methodologies. However, they provide helpful safety nets for group practices to ensure such compensation methodology complies with the group practice definition. Previously, CMS linked one of the deeming provisions for personal productivity bonuses to relative value units (RVUs) through reference to the methodology for establishing RVUs as set forth in an unrelated regulation.^[16] In the final rule, CMS removes the reference to methodology for establishing RVUs and reiterates that deeming provision allows productivity bonuses based on total patient encounters or RVUs personally performed by the physician. Importantly, CMS clarifies that the deeming provision is not meant to limit the payment of productivity bonuses currently permissible under the regulations. That said, personal performance is the hallmark of a productivity bonus, as is evidenced by that deeming provision.

The final rule provides confirmation that group practices may pay physicians a productivity bonus based on personally performed services without running afoul of the prohibition on compensation that directly takes into account the volume or value of that physician's referrals. The productivity bonus language also allows the physician to receive a productivity bonus based upon services furnished by members of the physician's care team "incident to" the physician's services and billed to Medicare as such. The services must meet the incident to requirements in order to be reflected in the productivity bonus payment. If not, those services cannot be included in a productivity bonus that directly relates to the volume or value of DHS referrals; they could only indirectly relate to the volume or value of DHS referrals.

CMS provides the following illustrative examples of allowable productivity bonuses under the group practice definition:

- A productivity bonus (or the portion of a productivity bonus) may be paid by a group practice to a physician in the group if the bonus is solely based on services personally performed by the physician (which are not referrals, even if they are DHS);
- A productivity bonus (or the portion of a productivity bonus) may be paid by a group practice to a physician in the group if the bonus is solely based on services performed by a member of the physician's care team that are not DHS; and
- A productivity bonus (or the portion of a productivity bonus) may be paid by a group practice to a physician in the group if the bonus is solely based on DHS ordered by the physician and furnished by members of the physician's care team incident to the physician's services and billed to Medicare as such.^[17]

Conclusion

While CMS afforded extra time to group practices to review their compensation methodologies and make

necessary revisions, many group practices may be struggling to make necessary changes. A careful review of the updated group practice regulation is advisable so that group practices ensure compliant compensation methodologies are instituted by January 1, 2022.

Takeaways

- The revised group practice regulation is effective January 1, 2022.
- The new volume or value standard that was effective January 19, 2021, will be applicable to group practices effective January 1, 2022.
- Profits from designated health services (DHS) furnished by a group practice that are derived from a physician's participation in a value-based enterprise may be distributed directly to that physician in the group, including profits from DHS referred by the physician.
- Group practices may not distribute DHS profits on a service-by-service basis; profits from all DHS of the group practice, or a component of at least 5 physicians, must be aggregated prior to distribution.
- The Centers for Medicare & Medicaid Services confirmed that a physician in a group practice may be paid a productivity bonus based upon services incident to their personally performed services as long as such services are billed to Medicare as incident to services.

1 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (December 2, 2020), <https://bit.ly/3g3eprL>.

2 42 C.F.R. § 411.355(b).

3 Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 895 (January 4, 2001).

4 42 C.F.R. § 411.352.

5 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492.

6 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,565.

7 42 C.F.R. § 411.354(d)(5)(i).

8 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,559.

9 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,558.

10 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,559–560.

11 42 C.F.R. § 411.352(i)(2).

12 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,561.

13 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,628.

14 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,579.

15 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,561.

16 42 C.F.R. § 411.352(i)(3)(i).

17 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,567.

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